

Applicants: Warren D.W. Heston, et al.  
Serial No.: 10/614,625  
Filed: July 2, 2003  
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#### REMARKS

Claims 24 to 35 are pending in the subject application, with claims 26-35 withdrawn from consideration. By this Amendment, applicants have hereinabove cancelled claim 25 without prejudice or disclaimer to applicants' right to pursue the subject matter of this claim in the future. In addition, applicant has amended claim 24 to recite, inter alia, the species methotrexate triglutamate previously recited in dependent claim 25. Support for the amendments to claim 24 can be found in the specification as originally filed at page 100, lines 21-25; page 91, line 35 to page 92, line 2; page 101, lines 22-32; page 102, lines 29-36; and page 51, line 36 to page 52, line 4. In addition, applicants have amended the Abstract to reflect the invention as claimed. Applicants maintain that the amendments to the claims and Abstract raise no issue of new matter, and respectfully request entry of this Amendment.

#### Declaration

In the October 20, 2006 Office Action the Examiner stated that a new oath or declaration in compliance with 37 C.F.R. §1.67(a) is required because it is noted that only three inventors signed the Declaration as compared to five listed on the original unsigned Declaration as well as on the first page of the specification, transmittal letters and other correspondence. The Examiner stated that applicants are reminded that a petition is needed to delete named inventors.

In response, applicant notes that the inventorship of a nonprovisional application for a patent is "the

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inventorship set forth in the oath or declaration as prescribed by §1.63, except as provided for in §§ 1.53(d)(4) and 1.63(d). If an oath or declaration as prescribed by §1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless applicant files a paper, including the processing fee set forth in §1.17(i), supplying or changing the name or names of the inventor or inventors." (37 C.F.R. §1.41, emphasis added).

Applicants further note that 37 C.F.R. §1.63 prescribes that the Declaration must be executed, i.e. signed. See 37 C.F.R. §1.63(a)(1). Accordingly, because the only signed Declaration filed by applicants in the above-identified application as prescribed by §1.63 was filed with the names and signatures of the three currently named inventors, the Declaration on file meets the necessary requirements and no Petition or Declaration according to 37 C.F.R. §1.67 is required. Thus, applicants maintain that the inventorship is correct as listed on the signed Declaration filed May 17, 2004 by applicants in connection with the above-identified application. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this objection.

#### Information Disclosure Statement

The Examiner stated that the Information Disclosure Statement filed March 30, 2004 in connection with the above-identified application fails to comply with the provisions of 37 C.F.R. §§1.97, 1.98 and MPEP §609 because, inter alia, page 1 contains what appears to be

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unpublished PCT documents and pages 7-8 contain unpublished U.S. Patent Applications.

In response, applicants note that the referenced documents were provided to the Examiner in order to avoid any issue whether applicants had complied with their duty of disclosure under 37 C.F.R. §1.56.

### **Priority**

The Examiner stated that applicants designated the instant application as a continuation of U.S. Serial No. 08/705,477, filed August 29, 1996, now U.S. Patent No. 6,569,432. The Examiner indicated, however, that the subject application is a continuation-in-part of the prior application.

In response, applicants respectfully traverse the Examiner's rejection. Applicants note that as specified in the Supplemental Preliminary Amendment filed October 31, 2003 in connection with the above-identified application which amended the priority paragraph of the above-identified application, the present application is already identified as a continuation-in-part. Applicants direct the Examiner's attention to the Public PAIR entry in connection with the above-identified application dated as scanned on 11-03-03 and entitled "Specification" of one (1) page. The amended priority paragraph states, in part, that the present application is a continuation-in-part of U.S. Serial No. 10/433,694, filed May 21, 2003, which is a continuation of U.S. Serial No. 08/705,477. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this objection.

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**Abstract**

The Examiner objected to the Abstract because it is three paragraphs.

In response, applicants have hereinabove amended the Abstract to a single paragraph.

**Claim Objections**

The Examiner objected to claim 25 as reciting non-elected species.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein cancelled claim 25.

**Claims Rejected Under 35 U.S.C. §112, First Paragraph (Enablement)**

The Examiner rejected claims 24 and 25 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for therapy comprising administering MTXglu<sub>3</sub> to cells comprising prostate specific membrane antigen, does not reasonably provide enablement for administering inhibitors of NAAG hydrolysis.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein amended claim 24 to recite subject matter that the Examiner has indicated in the October 20, 2006 Office Action to be enabled. Specifically, applicants have amended claim 24

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to recite that methotrexate triglutamate is administered to a subject so as to contact cells comprising prostate-specific membrane antigen and thereby inhibit release of glutamate by N-acetylaspartylglutamic acid (NAAG) hydrolysis in the subject. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Claims Rejected Under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 24 and 25 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner argued that the claims do not specify to what or to whom the agent is administered and that the method step is incomplete.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein amended claim 24 to recite that the agent, MTXglu<sub>3</sub>, is administered "to a subject." Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the documents identified below, items 1-9 of which are also listed on the attached Form PTO-1449 (**EXHIBIT A**). Items 1-7 are U.S. Patents or U.S. Patent Application Publications. No copies of these items are attached hereto as permitted under 37 C.F.R. §1.98(a)(2)(ii). Copies of items 8 and 9 are attached hereto as **Exhibits 1-2**. Item no. 10, a copy of which is attached hereto as **Exhibit 3**, is a co-pending unpublished U.S. Patent Application.

1. U.S Patent No. 7,070,782, Israeli et al., issued July 4, 2006;
2. U.S. Patent No. 7,105,159, Israeli et al., issued September 12, 2006;
3. U.S. Patent No. 7,037,647, Israeli et al., issued May 2, 2006;
4. U.S. Patent No. 6,953,668, Israeli et al. issued October 11, 2005;
5. U.S. Patent No. 4,569,794, Smith et al., issued February 11, 1986;
6. U.S. Patent Application Publication No. 2003/0105088, Tsukamoto et al., published June 5, 2003;

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7. U.S. Patent Application Publication No. 2006-0177450 A1, Israeli et al., published August 10, 2006;
8. Murphy, GP, (1996) Measurement of Prostate Specific Membrane Antigen in the Serum with a New Antibody, Prostate, (1996) 28(4):266-271;
9. Tino, WT, (2000) Isolation and Characterization of Monoclonal Antibodies Specific for Protein Conformational Epitopes Present in Prostate-Specific Membrane Antigen (PSMA), Hybridoma, 19(3):249-257; and
10. U.S. Patent Application Serial No. 11/480,319, Israeli et al., filed June 30, 2006.

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b) and a check including the amount of ONE HUNDRED AND EIGHTY DOLLARS (\$180.00) is enclosed herewith.

Applicants request that the Examiner consider the items listed and make them of record in the subject application.

In addition, applicants note that the Examiner has not returned initialed copies of the PTO-1449 forms submitted with applicants' Supplemental Information Disclosure Statements filed on December 6, 2004 and June 7, 2006. Applicants note that these Supplemental Information Disclosure Statements are of record in the PAIR system. For the Examiner's convenience, applicants enclose further copies of the PTO-1449 forms submitted with the Supplemental Information Disclosure Statements filed on

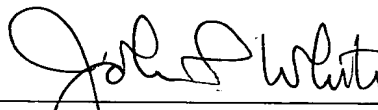
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December 6, 2004 and June 7, 2006 as **Exhibit B** and request that the Examiner initial them and return them to applicants.

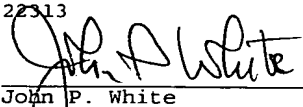
If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed total fee of \$405.00 including a \$180.00 Information Disclosure Statement fee and a \$225.00 fee for a two-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313	
	3/20/07
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